



University of Brighton

Rocking supine babies to sleep on the Easidream® mechanism:
a pilot study

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Abstract

Background and context: The University of Brighton was commissioned to assess the effectiveness of rocking supine babies to sleep on the Easidream® mechanism. The pilot study was conducted in a video-fitted, purpose built nursery. The aim of the study was to gather preliminary data to assess whether the mechanism enabled babies to stay lying on their backs and settle themselves to sleep.

Sample: In response to local advertisements, 14 parents recruited themselves and their babies to the study. All but 2 sets of parents joined the study because they considered their babies difficult to settle.

Design: Parents completed a sleep diary – adapted from the FSID Symptom Diary (2000) in the week prior to their baby being observed on the Easidream® mechanism in the nursery. Data extracted from the diaries showed that some babies were rarely left to settle themselves to sleep. Cuddling, being settled and often left to sleep in a car-seat, laid on a sofa or laid on/in a parental bed/using bedding that covered a baby's head were self reported as strategies to help their babies sleep. These are all in direct contrast to the Foundation for the Study of Infant Deaths 'best practice' guidelines (Young and Fleming 1999, Tonkin et al (2006).

The 14 babies were watched on the Easidream® for a total of 40 sleep episodes in the nursery.

Results: Average self-reported time to sleep at home was 15minutes (shortest of 6minutes, longest of 43minutes). Average time to sleep on the Easidream® was <17minutes (shortest <1min, longest 32mins). The key difference was the reduction in crying time on the Easidream® mechanism. During 29 of the sleep episodes the babies slept of the other 11 episodes the infants remained 'happily' awake. Average crying time at home was 18mins, on the Easidream® <1minute). Parents commented that their babies did not remain this settled when laid flat on a play mat or n a cot at home.

Conclusion: Parents placed their babies supine on the Easidream® and their comments indicated they were confident their baby was settled. All parents expressed pleasure at seeing their babies comfortable to either settle themselves to sleep or lay, flat on their back. The reduced crying time suggests that parents are more likely to adhere to the FSID (2009) and DOH (2009) current sleep policy /best practice guidelines.

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All babies cry when they are tired. This is something that parents find difficult (HV 2008, Russell et al 2003, Thompson et al 1996) and it is common for them to feel compelled to intervene to stop their baby crying (Russell et al 2003, Thompson et al 1996). As a result, many parents complain that they become sleep deprived themselves (Larkin and Butler 2000, Lee et al 2000). These difficulties are not new and most (mothers especially) learn to cope with the negative effects (Lee et al 2000, Swain et al 1997) by finding ways around the problem. This can mean parents alter their own sleeping habits (sleeping when their baby sleeps, for example) but, in the end, it usually involves helping babies learn to settle themselves to sleep in a cot (NHS 2008). Most advice acknowledges that crying is a normal part of this process (DOH 2006, FSID 2008, NSPCC 2008, NHS 2008). Since it is hard to deal with a baby who cannot be comforted (Leach 2003) it is common for parents to resort to alternative settling to sleep practices (Larking and Butler 2000, Lee et al 2000, Buultjens 2006, Crisp 2008). The difficulty is that the alternatives that are currently in common use also exacerbate the chances of a baby dying suddenly or unexpectedly (Blair et al 2006, Carpenter and Gardner 1990, Tonkin et al 2006). The habits they refer to with most relevance to this study are:

- leaving infants asleep in a bouncing chair/car seat/sling,
- leaving babies to sleep on a parental bed
- using bedding that covers a baby's head.
- adults falling asleep whilst feeding (for up to 2 hours) on a sofa/parental bed.

A new child care product, the Easidream® mechanism, was designed to gently rock (a head-toe movement) and roll (side-side) a baby to sleep¹. It was hoped that the motion of this mechanism, placed in a cot, would enable parents to leave their babies (aged between one and eight months) to settle to sleep on their backs without resorting to the practices that the DOH (2009) and FSID (2009) advise against. The University of Brighton was asked to run a pilot operational trial to assess the impact of the product on a small sample of babies. The findings of the study are presented here.

¹ A full set of the design drawings are available on the Easidream® web-site (www.easidream.com)

2 Background and Context

This section will examine the current research literature, policy and key debates that surround babies' sleep patterns, parental intervention and best practice guidance to minimise risks to babies when settled to sleep.

Babies routinely cry in response to being laid down and most parents find it difficult to leave their baby to cry themselves asleep in a cot. As a result, parents frequently experiment with a range of strategies to enable their baby to appear settled and happy. Sudden unexpected death in infancy (SUDI) or as it is more commonly known, cot death, is the most common cause of death in babies aged over one month (FSID 2009). Since 1991 there has been a 75% reduction in cot deaths and this is attributed to sleeping babies in the supine position - on the back (Blair et al 2006). Since the 1990's, epidemiological research has identified other risk factors which are mostly concerned with the environment of the place to sleep (Wilson 2007). As more becomes known about the specific risks The Foundation for the Study of Infant Deaths (2009) and the Department of Health (2009) update their recommendations to parents and so these are considered. Additionally, the research behind the on going 'Reduce the Risks' campaigns (DOH 2009, FSID 2009) is explored. With experience parents develop a solid sense of what is normal for their baby and quite quickly learn to respond to different types of crying (Sidey and Widdas 2005), so the cues parents respond to are discussed.

The literature was searched on PubMed, Pro Quest², CINAHL and Business Source Premier Data bases. The exception to the use of peer reviewed literature was a broad, Internet search to familiarise the researcher with the range of 'advice' that is widely available to parents. Otherwise only research based papers were included. Using the terms *cot death*, *sudden infant death syndrome*, *sudden unexpected death in infancy*, *sleep in babies*, *sleep*, *settling babies to sleep*, *how do babies fall asleep?*, *babies emotional moods*, *how do parents interpret their babies crying?*, *crying in babies*, *sleep deprivation in new parents* yielded over 10,000, wide-ranging responses. The abstracts were reviewed and accepted or rejected because of methodology, sample size or the fact that they were opinion pieces. To ensure the study reviewed only the most current literature the sleep related papers were all published after 1990 and included cot death related papers published between the years 1989-2009³. Only papers written in English were included. Data were extracted from the papers under the following headings:

- Infant crying patterns
- Settling babies to sleep

² At NHS Resources

³Since 1996 the focus of cot death research has included general infant care issues (FSID 2009) and so almost all of the included literature was published after this date.

- Parenting issues
- Advice to parents about settling crying babies to sleep
- Sudden Unexpected Death in Infancy
- Environmental issues

Key issues were identified and the literature is discussed in relation to these topic areas.

The term 'settling to sleep' (Leach 2003) is used to explain the processes involved with babies going/getting themselves to sleep. The term was preferred to 'falling' asleep or even 'fussing' (Sleep J 2002, 2003) because the phrase implies a situation parents can easily manage (Leach 2003). 'Settling the baby' was also the expression the parents, in this study, identified with most easily. The phrases 'cot death' and 'sudden and unexpected death in infancy' are used interchangeably (Wilson 2007). The terms 'happiness/happy/unhappy' are used to explain what parents reported about their babies' emotional mood⁴.

Babies cry when they need something (Leach 2003). Additionally, getting from a tired state to being comfortably asleep is quite difficult for small babies and most parents find it hard to believe that this type of crying doesn't necessarily mean that their baby is unhappy (Leach 2003, Wombourne HVs 2008, HV 2008). The difficulties may well be more adult than child related (Leach 2003), but because so many find it tiresome to leave a crying baby (HV 2008, Russell et al 2003), sleeping problems are the biggest problem for most parents (Morris et al 2001, Understanding Childhood 2008). Similarly well known is that the parents of wakeful babies become increasingly tired. Recognition that this can be harmful to both child and parent (Brett et al 1999, NSPCC 2008) means that these problems are more easily prevented than cured (Morris et al 1991, Nikolopoulou and St James-Roberts 2003).

Sleep is crucial to human health and sleep deprivation reduces the capacity to cope with stressful stimuli (Hodgson 1991, Southwell and Wistow 1995, Barclay and Lloyd 1996, Swain et al 1997, Nishihara and Horicuchi 1998, Larking and Butler 2000, Lee et al 2000, Buultjens 2006, Crisp 2008). Mothers who report feeling stressed by listening to a crying baby may also present with a high post-natal depression score (Barclay and Lloyd 1996, DOH 2007). More commonly, parents of babies who wake and cry continually report marital problems, excessive tiredness, and general stress (Brett et al 1999, NSPCC 2008) with most complaining about shorter sleep episodes and broken nights (Lee et al 2000, MacQueen and Mander 2003, Buultjens 2006). Brett et al (1999) suggest parents find crying babies additionally hard to deal with because of the tendency for professionals to give inadequate and sometimes wrong advice. They argue it

⁴Often, for example, parents used the remark to attach meaning to their baby's crying.

is especially unhelpful to try and reassure parents that sleepless children *outgrow* (p359) the problem. Whilst sophisticated, planned behavioural interventions (Sleep 2002, Nikolopoulou et al 2003) can lead to an improvement in settling behaviour for between 10% (Sleep 2002) and 21% (Nikolopoulou et al 2003) of babies by 12 weeks of age (Sleep 2002, NHS 2006); most professional advice (NHS 2008, Sleep 2002, 2003) suggests parents contain the problem with the use of baby slings/rocking in a pram/cuddling/going for a drive in a car (Wimbourne Health Visitor Team 2008, NSPCC 2008). These techniques can work in the short term but will often generate *sleep-onset association disorder* (SOAD) (Brett et al 1999, p359), for example, babies will fall asleep quickly when fed/held/rocked but cry continually cry when left in a cot.

Some commonly adopted sleeping practices (Miller et al 2008, FSID 2008) are associated with an increased risk of SUDI (Blair et al 2006, Young and Fleming 1999, Carpenter and Gardner 1990, Cote et al 2007). The practices that have particular relevance for this study are:

- leaving infants asleep in a bouncing chair/car seat/sling,
- leaving babies asleep on a sofa/parental bed
- the use of bedding that covers a baby's head.
- Parents sleeping with their baby in a bed or on a chair/sofa

The fact that these practices continue, regardless of FSID (2009) and DOH (2009) advice, may in part be explained by the detrimental effect of sleep deprivation on parental memory and flexible thinking (Hodgson 1991, Southwell and Wistow 1995, Barclay and Lloyd 1996, Swain et al 1997, Nishihara and Horicuchi 1998, Larking and Butler 2000, Lee et al 2000, Buultjens 2006, Crisp 2008).

In themselves the use of baby slings/rocking in a pram/cuddling/driving (Wimbourne Health Visitor Team 2008, NSPCC 2008) maybe acceptable becoming a problem when parents are excessively tired (Lee et al 2000, MacQueen and Mander 2003, Buultjens 2006). At these times the temptations to leave a baby asleep may be too much for parents to take their baby out of a sling/car seat or disturb them by removing clothes (Miller et al 2008, HV 2008). Similarly there is the problem of an exhausted adult falling asleep whilst cuddling a sleeping baby, a risk that is further increased when parents have consumed more than 2 units of alcohol or have taken drugs (Blair et al 1999). Parents are likely to feel additionally confused if health care professionals recommend, on the one hand, taking a baby for a drive to help settle them to sleep but also advise taking them out of the car seat (often in the process waking them) once home. In these circumstances it is easy to see why Miller et al (2008) found parents,

especially those from a deprived socio-economic background⁵, ignored such advice even when couched in terms to prevent cot death.

The risk of cot death is nine times higher for babies sleeping on their fronts (Fleming et al 2006, Young and Fleming 1999) and yet, despite the knowledge that babies placed on their sides are likely to roll into the prone position, maternity hospitals still set a dangerous trend because they recommend settling babies to sleep in this way (Blair et al 2005). As a result, perhaps, in the UK 20% babies are placed to sleep on their front with even more being settled on their side (Blair et al 2005, Wilson 2007). Additionally, in recent years there has been an increase in babies being found dead in a sitting position (Wilson 2007). Despite this and the *Back to Sleep* (FSID 1991-2009) campaigns that advocate babies should be settled to sleep on their backs, parents are willing to let their baby sleep in an alternative position of comfort.

Over heating is another important consideration in the prevention of cot deaths with recommendations that room temperatures be controlled between 18° and 21° (FSID 2009, DOH 2009). Parents are also advised to ensure they do not over-wrap a baby in bed wear or clothing (ibid) and that bedding should be limited to around 10 tog units (see appendix 5) or less. When room temperatures exceed 20°C parents are advised to remove layers of clothing (and bedding) from their baby (FSID 2009, DOH 2009). Of note, the effect of being over dressed and over heated is reduced for babies who sleep on their backs (Wailoo et al 1989, Young and Fleming 1999, Fleming et al 2006). A significant number of babies die with their head covered by bedding (Young and Fleming 1999, Wilson 2007). As a result parents are advised to place babies with their feet at the bottom of a cot and to tuck bedding securely at the foot end. This reduces the risk of a baby moving downwards and so underneath covers (FSID 2009). It also makes it unlikely that bedding will slip over a baby's head (ibid).

A key safety recommendation is that babies spend most of their time in the same room as adults, but settled in their own cot (FSID 2009). This enables parents to recognise and respond to changes in their baby. Additionally, parents are now encouraged to use a dummy as part of the settling to sleep routine (ibid). This recognises that to do so protects' babies (Fern et al 2005) and that the protection is greatest if the dummy is used for every sleep (Wilson 2007).

People have different ideas of what constitutes 'difficult behaviour' in relation to sleep/not sleeping or crying (Leach 2003, NHS 2006) and as a result parents do not all respond in a uniform way. Nevertheless, Hodgson (1991), Southwell and Wistow (1995), Barclay and Lloyd (1996), Swain et al (1997), Nishihara and Horicuchi (1998), Larking and Butler (2000), Buultjens (2006) and Crisp (2008) all agree that increasing adult tiredness, alongside a continuing infant dependence

⁵ 80% of SIDS deaths now occur in this group (Wilson 2007)

on adults to settle to sleep, has the potential for parents to resort to anything that will stop a baby from crying. The most common first-line responses to crying are picking a baby up, nappy-changing and attempting to feed (NHS 2006, DOH 2008, HV 2008). Whilst infants thrive (and ultimately cry less) with parents (mothers especially) who are sensitive to their unhappiness (Eisenberg et al 1998) an oversensitivity to cues can distress (and so lead to more crying) a baby (Leach 2003, Understanding Childhood 2008).

Most small babies are disturbed by the stimulus of their body's needs rather than ordinary, household noises (Leach 2003) and babies younger than 3 months usually settle in a range of environments. Many families try to encourage the settling process by using different handling, in order to indicate when it is time to be awake or asleep (HV 2008, NHS 2006, Leach 2003), but in general (unless there are too many, sudden changes) external noises or stimuli are unlikely to disrupt babies of this age (Leach 2003).

The Easidream® product was developed with all these issues in mind. The primary aim was to enable parents to settle their babies to sleep in a cot. A brief description is outlined here to illustrate the intended purposes of the product. This operational trial was designed to see whether the intended benefits of the product did have an effect on the settling behaviour of a small sample of babies.

2.1 About the Easidream

A rectangular, ventilated platform, the Easidream® was developed as an independent/retro-fitted piece of equipment that fits snugly into a mass-produced cot and beneath a range of standard cot mattresses. At the time of the study the mechanism was a prototype. The final product will be able to alternate between a side-side and head-toe movement but the study used two separate mechanisms. One of these was able to move from head to toe (rock), the other moved from side to side (roll). The motor size (reported on within University of Brighton internal documents) meant the prototypes were designed to stop working with a baby that weighed over 12kg. This equates to use for babies under 8 months. Similar age and weight restrictions are applied to other devices such as infant car seats (CAPT 2009, RoSPA 2009).

The depth of the original prototype platform used in this study was 12cm, limiting the upper age limit to 8 months⁶ because in reducing the depth of a standard cot-side, this could potentially make it more dangerous for mobile infants to climb or fall out of the cot.

⁶ design improvements mean the maximum height of the retailed platform is now 4cm

Babies between 4 weeks and 8 months were recruited to the study. This was in recognition that the early weeks with a new baby are difficult for parents to manage (Leach 2003, NHS 2006, HV 2008). As a result, it was thought unreasonable to ask parents to bring their newborns to the study site.

The final important design feature was the cut-off system whereby the mechanism stopped at 30 minutes. It was hoped this would encourage parents to return to a crying baby instead of over-relying on a continually moving mechanism. The importance of this kind of regular parental supervision also underlined the importance of the *share a room with me* (FSID 2009) message.

Therefore the overall aims of the operational trial were to establish whether when lying on an Easidream® mechanism babies would:

- Stay lying on their back
- Settle to sleep.

The specific questions of the pilot study were to establish:

- Does the motion of the Easidream® mechanism enable babies to go to sleep sooner than when left in a motionless cot?
- Do babies stay asleep on their backs?
- How long do babies stay asleep?
- If babies do not go to sleep whilst on the mechanism what behaviour is observed?

The next section of the report sets out the design of the study and the methods by which data were collected and analysed.

Study Design

This was a pilot operational trial of a small number of babies in a nursery. Comparative data were collected. Parents were invited to record sleep diaries of their babies settling and sleep patterns one week prior to spending time on the Easidream® product. The settling behaviour and sleep patterns once on the Easidream® were then recorded by the researcher in field notes. Data were analysed using descriptive statistics and supplemented by observational memos of interactions with the parents. 12 parents said they had recruited their baby to the study because they were finding it difficult (at home) to settle him/her to sleep in a motionless cot. 2 babies were watched once each, 2 more than twice⁷ and all of the others were observed on 2 occasions.

3.1 Recruitment

Publicity about the study prompted parents to contact the researcher or Business Development Manager (University of Brighton) to find out more information. In this way, no one individual was coerced into participation or subject to undue social pressure to be involved in the study. Notification of the study was made in the following arenas:

- A stand at a commercial Baby Fayre in the South of England. University of Brighton Business Services representatives attended and demonstrated an Easidream® mechanism. Parents had a chance to meet with the design/engineering team⁸ of the product and the entrepreneur. Information sheets explaining the study (appendix 3) were on display and families who made enquiries were asked to contact the primary researcher.
- Poster advertisement (also appendix 3) displayed at the research site.
- Local newspaper and radio advertisements.
- And finally, by word of mouth.

The study's inclusion/exclusion criteria were specifically that:

- all babies needed to be aged between one and eight months of age
- all babies needed to weigh less than 12kg
- all babies needed to be physically well
- no baby was taking medication

An information sheet (appendix 1) was sent to all families, by post once they had consented to participate in the study. Parents were sent a self-report Sleep Diary (UoB, 2008 - appendix 2) to complete throughout the week before the study

⁷ The data about the sleep episodes for these babies are recorded as 'repeated' sleeps.

⁸ Part of the South East Knowledge Exchange programme, supported by the University of Brighton Business Services team.

as well as on the days when the baby had spent time on the Easidream® product.

The parents of the 14 babies were invited to pre-book a sleep episode within a 3 week period. They were able to select the most convenient day and time of day for them and their baby. It was difficult to strictly plan when and how the babies would sleep (Crisp 2006, DOH 2001) and, as the trial wanted to assess how babies settled on the Easidream® when they required sleep, some flexibility around booking was required. The opportunity to re-book sleep episodes enabled babies who were ill during one part of the study to be observed once they had recovered.

Before they brought their babies to be studied, the details of what they were required to do was relayed to parents by telephone and in a follow up letter/information sheet. This included sending them a copy of a blank consent form (appendix 4). On the day of the study the process was re-visited and all parents were asked to sign a consent form before the baby was placed on the Easidream®. With each subsequent sleep episode they were asked to sign consent again (appendix 4).

Parents were aware that they had the right to terminate their baby's participation at anytime.

As the operational trial took place in the nursery parents were offered reimbursement for their travel costs. Instead of asking parents to submit travel claims a 'one off' high street retail voucher was given as a gratuity. Advertising did not alert parents to this.

3.2 Sample

A convenience sample of 16 babies was recruited to the operational trial. However, as a result of incomplete data sets returned to the researcher, the analysis was based on data relating to 14 babies.

Babies were on average twelve and a half weeks old (youngest 4 weeks, oldest 25 weeks) and weighed on average 5.8kg (lightest 3kg, heaviest 8kg).

One baby had been born with bilateral talipes. As a result, both of the infant's legs had been immobilised by a plaster cast since birth. This cast had been replaced with an immobilising splint 3 days before the first sleep episode. The researcher was not aware of this medical history until the family attended for the first sleep episode. The decision to include this baby in the study was because the condition was not considered an illness and the treatment was 'normal' for that baby and the family since birth.

The parents of two babies volunteered to bring their babies for more than 2 sleep episodes.

At the time of the study all babies were living with their birth parents and so they are referred to throughout this report as family/parents rather than parents/carers.

3.3 Methods

3.3.1 The Sleep Diary

Although self-reporting can raise issues around accuracy (Polit et al 2001), this approach was chosen to gauge the 'normal' sleep routines and settling behaviours in the home to those observed in the nursery and on the Easidream®. In order to take account of babies' varying sleep patterns (DOH 2006, Brett et al 1999) parents needed to have flexibility in the way they explained their infant's sleeping habits. At the same time it was important to be able to quantify the data sets. The Diary was adapted from the FSID (2000) *Symptom Diary*. The validity and reliability of the FSID tool have been tested on over 10,000 data sets (Waite et al 1998, 2008). Changes to the original tool (questions were related to sleep rather than illness) were considered low risk in affecting the validity and reliability of the adapted tool used in this study.

Like the FSID tool, the Department of Health's Personal Child Health Record (DOH 2006) and the Baby Check scoring system (Thornton et al 1991) the Sleep Diary guided parents to respond to specific questions about their babies sleep behaviour and to comment as to whether they considered this to be 'usual'. Based on an assumption that parents are usually the best judge of this (Leach 2003, HV 2008, DOH 2008), they would be able to record activity more reliably than a researcher in the home. These data provided the baseline of what parents considered to be the usual sleep pattern for their baby against which comparison could be made whilst the baby was placed on the Easidream® product.

3.3.2 The Observational Study

The 14 babies were watched on the Easidream® for a total of 40 episodes. 2 babies were watched once each, 2 more than twice and all of the others were observed on 2 occasions. All babies who were watched more than once were observed on both a rocking and a rolling mechanism. All episodes took place in one room and were video-taped via two, fixed cameras that monitored shots of both study cots continuously, alternating between the cameras.

On a few occasions and for reasons to do with the motor of the prototype, babies were placed in the middle of the cot but mostly they were placed as recommended (FSID 2009, DOH 2009) with their feet to the bottom of the cot. All babies were covered in a total (including clothing) of 10 tog units or less (FSID 2009, DOH 2009) and all were watched. Babies were settled to sleep with a dummy 100% of the time and all were laid down and remained supine (lying on their back) when left in the cot.

A member of the design/engineering team was present to supervise the working of the Easidream® because only the parts, not the prototype itself, were tested to British standards. The engineers/designers checked the mechanism at the

beginning, middle and end of each day. There were no incidences of mechanical malfunction. Occasionally, between episodes of sleep the designers/engineers did some mechanical work on the motor. They and the researcher were careful to check that none of these interventions altered the rhythm/degree of movement or the rock/rolling motion of the cot.

The layout of the sleep room was deliberately chosen to re-create a nursery environment (Polit et al 2001). It was spacious enough for parents to remain comfortable with their babies but was small enough to be a cosy space. Two mechanisms were set beneath two cots and were watched in the same room. At times 2 babies (and their parents) were in the room simultaneously and on these occasions space was limited. It was therefore especially important that a pleasant, comfortable waiting area was set aside for parents to use. This was fully equipped with drink making facilities and infant nappy-changing facilities were available.

All parents were asked to settle their baby as they would normally do at home and in all cases the degree to which a baby was considered to be settled was measured by:

- The parents behaviour (ie they did not return to the cot and pick up the baby)
- How little the baby cried.

Data were recorded in hand written field notes and compared to the parents' self-reported narratives and observation of video data of the Easidream® sleep episodes. Parents were aware of the video-recordings and the fact the researcher took notes. The process of taking field notes was designed to be as unobtrusive as possible to reduce any observer effect on performance (Polit et al 2001). For example, it was crucial that there was no attempt to accelerate the settling to sleep process in order for parents to follow as similar a routine when at home even though they were in a simulated environment being observed. As a result it sometimes took time for babies to be ready to be settled for the first sleep. Such delays were less obvious during second or subsequent sleep episodes as parents became more comfortable and familiar with the experience.

Time in the sleep room was used to informally interview parents and to expand on aspects of their self-reported accounts of the baby's sleep episode. The type of issues discussed included:

- When (and how) it was recognised that each baby was asleep
- How long each baby slept for
- What happened (in terms of movement/noises) if a baby did not sleep
- Specific noises each baby made (crying/gurgles/grunts etc) as well as when and how the crying/gurgling/grunting etc became quieter or stopped

- Specific movements (head/limbs/whole body), how these became slowed as well as when and how they stopped
- Interventions made by parents during study episodes
- How parental interventions affected what happened – especially if this resulted in the baby not settling to sleep on the Easidream® mechanism but being placed on it later, asleep.

3.3.3 Video-Recordings

Field notes produced data that enabled the identification of consistent themes. This was backed up by video records that enabled the observer to cross-reference and check the accuracy of the field notes. Filming was in black and white and had a recorder to monitor sound; this did not however compromise the clarity of the record.

3.4 Data Analysis

Data sets were coded to ensure anonymity and all electronic data were secured against unauthorized access. Taking full account of the purpose for which the study was commissioned a combination of tools was used for the analysis. An initial scrutiny of the field notes led to a coding framework that reflected the key themes. Following coding both field notes and the parental narratives were thematically grouped.

A sample of 4 sleep episodes was reviewed by an experienced, specialist professional. This enabled verification of the analytical framework and thematic results generated from the remaining videoed sleep episodes. Narrative accounts recorded in the field notes (cross-referenced with video-tape evidence) and some aspects of the Sleep Diaries were subject to thematic analysis. The majority of Sleep Dairy recordings were subject to Descriptive Statistics to produce an overall summary of *typicalness* (Polit et al 2001, p335) in the sleeping patterns. The highlights of this material are presented as aggregated data (appendix 6).

3.5 Ethical Issues

Prior to the study being run the following checks were made and approvals sought:

- Advice (from the Medicines and Healthcare Regulatory Agency (MHRA) determined that (since the Easidream® is not used to treat a medical condition) the sleep episodes were not classed as clinical trials. Further

advice (from the Centre of Research at the School of Nursing and Midwifery) recommended the study episodes were best classed as operational trials.

- Ethics approval was sought via the Faculty of Health and Social Science (FREG) rather than their counterparts within the Faculty of Science and Engineering because of the special concerns of working with babies.
- The actual participants were babies so they had neither the competence nor ability to give their own informed consent. Consequently this had to be obtained via their parents.
- It was important to ensure parents understood that some aspects of their self-reported sleep episodes as well as the field notes would be used to discuss the effectiveness of the Easidream®. However, because the number of participants was small, extra precautions (referring to parent/parents/families rather than mother/father as well as disguising some field study details) were taken to protect individual's identities.

Once the results had been distributed to the commissioner of the study parents were able to access the report on the Easidream® website.

4 Results

This section presents a summary of the key findings. The data were evaluated using Descriptive Statistics. Quotes from parents have been selected because they typically represent a perspective shared by others unless a different perspective is indicated.

4.1 Sleep Diary

In the week before the study (as well as during the 2 week study period) 14 parents' documented information about their baby. This resulted in a combined total of 520 home-sleep entries⁹. 6 data sets were returned complete. 8 of the Diaries (286 entries) contained some (26 in total) confusing information. For example, some diary sheets had the time of lying down as well as waking logged but had documented no other information. In other Diaries one response in a Diary entry contradicted another for the same sleep episode, or an entry was contradicted during informal interviews. With one exception¹⁰ these were considered to be minimal errors, most likely the result of tiredness or distraction, so the 26 (5%) reports were excluded from the analysis process. The other 494 (95%) Diary accounts are reported on.

It is now clearly understood that some environmental factors as well as infant care practices are hazardous to small babies (Young and Fleming 1999, Wilson 2007). Despite this 75% of British parents behave in a way that suggests they are still not aware of these cot death risks (FSID 2008). Similarly, in the case of these parents 13 (of the 14) recorded an average of 36% of times when they had put/left their baby to sleep in a position that FSID/DOH (2009) specifically advise against. Only one of the Sleep Diaries reported that a baby was always settled to sleep in a cot. None of the self-reports' recorded that babies, once asleep, were routinely laid down in a cot. In the Sleep Diaries parents identified that during the 3 week study period they had:

- left infants asleep in a bouncing chair/car seat/sling,
- left a baby to sleep on the parental bed
- used bedding that covered the baby's head.
- fallen asleep whilst feeding (for up to 2 hours) on a sofa/parental bed.

⁹ Each entry documented a separate sleep episode.

¹⁰ The parents of one baby reported in the Sleep Diary that their baby was always put to sleep in a cot something they contradicted at informal interview when they reported they were *never* able to use a cot. Observations about this are recorded in the Discussion section of the report.

The study set out to establish if the motion of the Easidream® would enable babies to settle to sleep sooner than when left in a motionless cot. Of the self-reported home sleeps, 351 (71%) did NOT relate to being settled to sleep in a motionless cot. Furthermore, 173 (35%) of the total home sleeps were the result of the babies either falling asleep when feeding or being cuddled to sleep by an adult.

Crying time was/is an important indicator of how settled or happy babies were/are. According to parental reports the average time taken for all of the study babies to go to sleep at home (cuddled etc or not) was 15 minutes (shortest 6 minutes, longest 43 minutes). Sleep Diaries record an average crying time of longer - 18 minutes (shortest 1 minute, longest 60 minutes) on the occasions they were left to settle themselves (not being cuddled/in pram/car seat/sling/bouncing chair/parental bed/feeding). The average time taken for babies to be asleep for cuddled etc sleeps was 14 minutes (shortest 30 seconds, longest 120 minutes).

The data sets for the babies who went on to settle to sleep on the Easidream® mechanism indicated that the average time these babies stayed asleep at home (during the day) was 72 minutes (shortest 20 minutes, longest 200 minutes). The Sleep Diary for one of these babies did not show any daytime sleeps¹¹.

In diary narratives 2 sets of parents mentioned picking their babies up, (in response to crying) in order to re-settle them. In direct contrast, when asked about this face to face, parents stated they always lifted a crying baby in order to help them re-settle to sleep.

4.2 Sleep episodes on the Easidream®

Babies slept on 29 (72.5%) occasions¹². During the other 11 (27.5% and non-sleeping) episodes infants remained happily awake. All babies stayed (happily) lying on their backs. The average time taken to be asleep was less than 17 minutes (shortest less than 1 minute, longest 33 minutes). On average they stayed asleep for 37 minutes (shortest 7 minutes, longest 132 minutes). This compared to an average of 72 minutes (shortest 20 minutes, longest 200 minutes) that these babies stayed asleep at home. The average crying time (for all babies) for these sleeps was less than 1 minute (shortest 0, longest 10 minutes).

¹¹ Video records and field notes confirm that the parents of this infant said that their baby *never* slept by day.

¹² Many of the families lived enough of a distance from the nursery to need to drive/bus/walk to the study site. On 8 of these occasions a baby slept during the journey.

On 10 (25%) occasions parents requested the study to be stopped because they thought their baby was not going to settle to sleep¹³. On 4 (10%) occasions parents lifted their sleeping baby to terminate the study.¹⁴

The average time that all babies lay awake and happy on the Easidream® was 18 minutes (shortest 3.5 minutes, longest 31 minutes).

Babies cry in order to persuade their parents to pick them up (Thompson et al 1996). Although none of the Sleep Diaries specifically mentioned lifting babies the field notes and video recordings indicated that when at home all of them did so. During the study 7 parents lifted their baby at the first sign of crying. The other half did not lift their baby at all. Of the parents who lifted, 4 did so to feed/wind/nappy change. 3 lifted and comforted their baby before settling them back in the cot. Of the parents who lifted their baby 5 did so more than twice (to feed/change a nappy/resettle) with an overall average of more than once but less than twice. Each time parents re-settled their babies supine, replaced their dummy and made comments that indicated they were confident their baby was happy.

All parents commented (on the video-tape and for field notes) that when left in a similar position (without interaction) at home - alone, laid flat, motionless and supine on a play mat/in a cot - their babies did not remain as settled.

4.2.1 Repeated sleeps

2 babies were observed on the Easidream® more than twice. The narratives from these sleep diaries as well as the evidence of the video-records and hand-written notes show that the parents of both babies considered that (at home) their infants settled easily to sleep. One baby was watched on 4 occasions, the other on 9. The baby that was watched most often was being cared for at the nursery for each of these episodes. The study coincided with the first 9 days at nursery for this baby. The inclusion of these babies enabled the study to begin to consider whether frequent use of an Easidream® mechanism might have a negative affect:

- on babies who have already matured to settle themselves to sleep.
- by making them bored of lying on an Easidream® (reverting to crying)
- by stopping a baby with an already settled routine being able to settle in a non-moving cot.

¹³ Reasons given were that they either didn't believe their baby needed to sleep or that they had other commitments that required them to leave.

¹⁴ Reasons given were that babies had slept for longer than parents had expected them too.

Video recordings and field study notes (for both babies) showed that all of their sleeps episodes on the Easidream® followed a similar pattern.

It is important to consider if babies continued/reverted to crying to be cuddled once the novelty of being laid on the Easidream® had worn off. Sleep Diary narratives, video recordings and field study notes reported that before the study the parents (of both babies) considered their infants had a 'good/easy' settling to sleep routine. Video records and field notes showed that neither baby cried or was considered to be unhappy (by their parents). Sleep Diaries showed that at home one baby was usually asleep in 6 minutes but, because of crying, although often put into a cot once asleep, was never left to settle to sleep this way. Settling to sleep on the Easidream® took more time - an average of 21minutes - (minimum 10mins/maximum 33 minutes) but (in contrast to the reporting at home) the baby lay happily in the cot throughout the wakeful time. Sleep Diary records showed that it was quite common for this baby to be left asleep in what FSID/DOH (2009) consider to be dangerous situations.

Not all of the Sleep Diary records for these 2 babies clarified where they were left asleep. Parents did indicate they were left settled in a cot for 52% of the home reported sleeps. On these occasions the parents reported the baby settled to sleep in an average of 12minutes. This compared to an average of 5 minutes (minimum 3mins/maximum 8mins) on the Easidream®. Cuddling was the option used 22% of the time if either of these babies needed parental intervention to sleep at home. Neither was cuddled whilst settling to sleep on the Easidream®. When not cuddled (or other intervention) at home these 2 infants were reported to cry for an average of 7.5 minutes (minimum 2mins/maximum 20mins). On the Easidream® crying time was for an average of 2mins (minimum zero/maximum 3mins). Both sets of parents kept coherent sleep diaries (135 episodes in total) throughout the 12 days study period, neither reported a negative change in their baby's sleep patterns.

4.2.2 Head covering

Since the end of the 1980's the drive to reduce the amount of *too hot* (Blair 2008, FSID 2008 p1) babies has been a cornerstone of the Department of Health campaigns to reduce the amount of cot deaths in England and Wales. A key aspect of this message is to do with reducing the tendency for parents to keep their baby's head covered (most often with hats/bedclothes) in indoor situations. One baby arrived for the second sleep episode with an item of bedding the family used to fit tightly around the baby's head in order to settle the baby. Although not specifically identified in the diary, the video-tape records and field notes showed the parents regularly used this to help the baby settle alone in a cot at home. Although for one of the sleeps (at the parent's request) the baby slept with the bedding in place, video-recordings and field notes showed that as well as

discussing the dangers of covering a baby's head, the total tog value of the layers of clothing/bedding were accordingly adjusted. One sleep episode for this baby on the Easidream®, without this item of bedding, took 7mins for the baby to be happily settled to sleep. The other sleep with the bedding took 10 minutes. This compared with the home reported sleeps with the bedding that took, on average, 10 minutes (shortest 0, longest 15 minutes).

4.2.3 Laying on a 'switched-off' Easidream® mechanism

The Easidream® was designed with a 30 minute cut-off feature in the hope it would encourage parents to return to a crying baby instead of over-relying on a continually moving mechanism. So, the mechanism was switched off for 15 of the 40 sleep episodes to observe if/how babies responded to the stopping of the movement. This was the least structured aspect of the study (the prototype did not have an automatic switch-off mechanism) but the reactions of babies were noted. On average the babies had been asleep for 15 minutes (shortest 2 minutes, longest 50 minutes). They woke on average 41 minutes later (shortest 1 minute, longest 135 minutes). On 2 of these occasions the baby's parent woke their baby because they needed to leave (after 34 minutes and 53 minutes). On 2 occasions babies stayed awake until the Easidream® was switched off. Both remained happy until their parents interrupted the study to leave. For one baby this was 5 minutes after the mechanism was switched off, for the other it was 20 minutes later.

4.2.4 Parent related issues

Parents were aware they had the right to terminate the study at any time. On 14 (35%) of the 40 sleep occasions parents requested the study to be stopped before either their baby had slept or woken from sleep. Reasons given for lifting their baby were because he/she had slept for longer than the parents had expected or because they felt their baby was unlikely to sleep because they had already slept on the way to the study. These events are reported on. On 10 occasions parents asked to terminate the study whilst their baby was still awake. On 4 further occasions parents asked to lift their sleeping baby in order to leave. In all but one case these events were explained by the parent saying their baby had either slept on the way to the study (and they did not expect them to sleep) or because the baby had stayed asleep for longer than the parent expected (and they needed to leave for another appointment). Mostly parents made a great effort to explain that they hadn't expected their baby to be so comfortable or that they had not expected to be at the study site for so long. On one occasion a baby had been brought to the study (by both parents) early for the appointment that they had pre-arranged. The parents explained that the baby had fallen asleep in the car and they thought they had better come into the study site to make it more likely their baby would settle for the study. Both Easidream® cots

were being used by other babies at the time and the family had to wait until one became available. Despite the use of a waiting room one of these parents became increasingly anxious about the need to wait. Both the video-tape and field notes show that 39 minutes into the study the parents had a conversation between themselves where one said they wanted to leave, the other to stay. One minute later they asked to leave. The parent who had wanted to stay came back with the baby, alone, for the subsequent, pre-arranged sleep episode.

Highlights of these results are also summarised in the table (appendix 6) that illustrates by case the aggregated data for each baby.

Discussion

This section draws on the results of the project, along with the literature review in order to comment on the key findings. These are discussed in terms of the original operational trial questions. It has already been established that all participants used a dummy to settle to sleep and stayed laying on their backs 100% of the time so these aspects of the results are not separately discussed.

5.1 Did participants go to sleep?

Despite the fact that on 8 occasions (20% of the time) babies had slept immediately before arriving to be studied, the results showed that of the 40 times babies were placed on an Easidream® mechanism they slept 72.5% of times, even when parents did not think they were tired enough to do so.

When settling to sleep on the Easidream® parents reported their babies seemed happier than when settling to sleep in a non-moving cot at home. The key measurement of happiness was the extent to which babies did not cry. In addition, video-taped records and field notes repeatedly showed parents talking about how settled their infants were in comparison to how settled their baby was at home. Sleep Diary accounts confirmed this.

The reduction in crying times is important because the pitch of a crying baby has evolved to make adults do something (Russell et al 2003, Thompson et al 1996). This innate response to crying becomes a problem when parents do anything to stop it (Miller 2008, Cote et al 2007). In the case of these parents 'anything' included rocking/cuddling, taking babies into the parental bed, being left sleeping in an infant car seat and the covering of a baby's head. These are all preventable risk factors in terms of sudden unexpected death in infancy (DOH 2009, NSPCC 2008, NHS 2008, Blair et al 2006, Fleming et al 2006, Tonkin et al 2006, FSID 2009). Surveys (Miller et al 2008, DOH, 2008 FSID, 2008) suggest most parents take this type of risk knowingly. Reasons given are most often to do with the fact babies settle to sleep more easily (Wilson 2008). The field notes suggest none of these parents were surprised by the FSID recommendations when they were discussed with them. Brett et al (1999), NSPCC (2008), NHS (2008) and DOH (2008) recognise parents are also most likely to take this type of risk when they are desperately fatigued. The parents in this study self-reported regularly compromising safety recommendations in a way that Miller et al (2008), DOH (2008) and FSID (2008) suggest is common, in an effort to settle their baby to sleep with the minimal amount of crying.

Happiness in the context of the study was additionally measured by the fact parents felt less need to pick their babies up (in order to comfort them) than they reported they did at home. These observations are supported by the video tape and field notes. For example, 12 parents told the researcher that they regularly lifted (in order to re-settle) a crying baby at home. In contrast, when settling on the Easidream® only half of the parents (7) lifted their baby. 4 parents lifted to feed or nappy change and 3 lifted in order to cuddle and re-settle only.

5.2 If participants do not go to sleep what happens?

Home sleeps (71%) were achieved without a baby being left to settle in a cot. Video-records and field notes confirm the Sleep Diary narratives that the decision to lift babies at home was most usually in response to continued crying. Parents confirmed they used crying as a measure of their baby's happiness. The average crying time (when settling to sleep on the Easidream®) was less than 1 minute (shortest 0, longest 10 minutes). If the reduced crying-responses of the babies in this study are typical it seems likely the use of an Easidream® mechanism will encourage parents to place their babies down to sleep (in the supine position and in their own cot) safely.

Bee and Boyd (2006) explain that much of how babies respond to their environment is learnt behaviour. It was therefore important for the study to take advantage of the fact that 2 parents offered to let their baby be placed on the Easidream® more than twice. It enabled the study to begin to consider if 'learning' to sleep on an Easidream® would negatively affect the home practices of babies whose parents considered them to already have a good ability to settle themselves. Whilst it is important to avoid overstating the importance of 13 observations about 2 babies these results showed that as well as being placed supine on the Easidream® both babies settled 'well' according to their parents' comments. Furthermore, at no time (during the 2 weeks of the study period) did either of these babies' parents report (via Sleep Diary narratives or for the field notes) any noticeable change in their child's home sleep patterns. The parents of both babies' said that, they felt, their baby had enjoyed the experience and both volunteered to return for more watched episodes of sleep.

The home experience for one family was that in order for their baby to settle happily to sleep they felt they needed to use an item of bedding to cover their baby's head. It gave what they called a sense of security. This is in direct conflict with the FSID (2008) recommendations. Field notes showed that the parents said they used this item of bedding because they believed it made their baby more comfortable. These notes also recorded the parents' pleasure at seeing their baby settled without the bedding. Field notes suggested these parents were happy to notice what they perceived to be a reduced crying time when their baby settled on the Easidream®. Other comments showed that they would be prepared to settle their baby to sleep without the bedding if they felt they had an alternative option.

The findings from this small scale pilot study indicate that the parents were confident their babies were more settled when lying on an Easidream® than when laid flat in a conventional cot and that the everyday use of an Easidream® may make it more likely for them to settle their babies safely. However, further research is required to assess whether or not parents use the Easidream® to facilitate sleep in the same way at home as they did in a simulated nursery under observation.

5.3 Limitations of the study

The validity and reliability of self reported Sleep Diaries is an aspect that requires further research. In 86% of Sleep Diaries returned to the researcher, parents omitted to mention what they later recalled in informal interviews, to be a routine habit of picking up their crying baby in order to re-settle them. This contradiction highlights a problem shared by most self-report methods of research (Polit et al 2001). To pick a baby up in response to crying is not considered to be risky behaviour. Instead it seemed more likely this practice was so common place and instinctual that parents failed to report it. In contrast one family reported that their baby was always settled to sleep in a cot in the Sleep Diary but at informal interview claimed their baby never settled in a cot. Since all child-health care advice recommends a cot as the only safe place for babies to sleep it is possible this family felt the need to tell the researcher what they thought they expected to hear, rather than give a factual account. Naidoo and Wills (2001) believe people will only share information with health care professionals once they feel they can trust them. So, if repeated, the researcher would design indirect contact with families, including an interview about normal sleep patterns, prior to inviting parents to complete a self-report Sleep diary.

5.4.1 Areas for further research

The findings from this pilot study offer encouraging results that need to be replicated in a larger scale study. However, tentative and limited by self-selection bias and scale, the findings reported here indicate that babies who are settled on an Easidream® do cry less often when settled to sleep. This may reduce parental anxiety, exhaustion and stress. If the results of this study are repeated in the general population the Easidream® mechanism may offer parents' an alternative way of successfully settling their babies to sleep in the recommended safe environment of a cot.

A replication study would need to include babies younger than one month and similarly, because of safety changes in the depth of the mechanism (Forbes 2008) the new mechanism should be tested on babies over 8 months.

References

- Barclay L M and B Lloyd (1996) The misery of motherhood: alternative approaches to maternal distress *Midwifery* vol 12 pp136-139
- Bee H and D Boyd (2006) *The Developing Child* Pearson International
- Blair P S, P J Fleming, I J Smith, M Ward Platt, J Young, P Nadin, P J Berry, J Golding, CESDI SUDI research group (1999) Babies sleeping with parents: case-control study of factors influencing the risk of the sudden infant death syndrome *British Medical Journal* vol 319 pp 1457-1462
- Blair P S, E A Mitchell, E M A Heckstall-Smith and P J Fleming (2008) Head covering a major modifiable risk factor for sudden infant death syndrome: a systematic review *Archives of Disease in Childhood* vol 93 pp 778-783
- Blair P, P Sidebotham, P Berry, M Evans, P Fleming (2006) Major epidemiological changes in sudden infant death syndrome: a 20-year population-based study in the UK *The Lancet* vol367,issue 9507, pp314-319
- Blair P S, M Ward Platt, I J Smith, P J Fleming and CESDI SUDI Research Group (2006) Sudden Infant Death Syndrome and the time of death: factors associated with night-time and day-time deaths. *International Journal of Epidemiology* vol 35 pp1563-1569
- Brett R, J W Mayfield, R H Kuhn (1999) Clinical assessment of child and adolescent sleep disturbance *Journal of Counselling and Development* vol 77
- Buultjens M (2006) *When giving life starts to take the life out of you: women's experiences of depression after childbirth* School of Public Health, La Trobe University, Victoria, Australia
- CAPT (2009) www.capt.org.uk
- Carpenter R and A Gardner (1990) Environmental findings and sudden infant death syndrome *Lung* vol 168 pp358-367
- Cote A, A Bairam, M Deschenes, G Hatzakis (2007) Sudden infant deaths in sitting devices www.archdischild.com
- Crisp S (2008) *How much sleep do children need?* www.netdoctor.co.uk/health_advice/facts/childrensleep.htm
- Department of Health (2001) *Birth to Five Years* DOH
- Department of Health (2006) *Personal Child Health Record* DOH
- Department of Health (2007) *MCH 09-06: A Randomised controlled trial to compare alternative strategies for preventing infant crying and sleeping problems in the first 3 months of life* www.dh.gov.uk/en/Researchanddevelopment/A-Z/Motherandchildhealth/DH_4
- Department of Health (2009) *Reduce the Risk of Cot Death* DOH
- Eisenberg N, A Cumberland, T Spinrad (1998) Parental socialization of emotion *Psychological Inquiry* vol 9, no 4 pp241-273

Fern R Hauck, Olanreqaju O Omojokum, Mir S Siadaty (2005) Do pacifiers reduce the risk of sudden infant death syndrome? A Meta-analysis *Pediatrics* vol 116, no 5, pp 716-723

Forbes A (2008) Extracts taken from an e-mail correspondence on 9th September 2008, Maddison Ltd

Fleming P, P Blair, J McKenna (2006) New knowledge, new insights and new recommendations *Archives of Disease in Childhood* vol 91 pp799-801

FSID(2000) *Daily Symptom Diary* FSID

FSID (2008) *Keep an eye on your baby's room temperature* www.sids.org.uk/your-baby.html

FSID (2008) *Majority of parents fail to identify cot death hazards* www.fsid.org.uk/mothercare-poll-press.html

FSID (2009) *Reduce the Risk of Cot Death* FSID

FSID (2009) *Sleep Safe, Sleep Sound, Share a room with me* FSID

FSID (2009) *About FSID* www.fsid.org.uk/cot-death.html

Hart C (2001) *Doing a Literature Search: A Comprehensive Guide for the Social Sciences* Sage

Health visitors (2008) *Stopping the baby crying* www.healthvisitors.com/parents/stop_crying.htm

Hodgson L (1991) Why do we need sleep? Relating theory to nursing practice *Journal of Advanced Nursing* vol 16, no 12 pp1503-1510

Horne J (1998) *How much sleep do we need?* www.lboro.ac.uk/departments/hu/groups/sleep/news/telegraph2.html

Larkin V and M Butler (2000) The implications of rest and sleep following childbirth *British Journal of Midwifery* vol 8, no 7 pp438-441

Leach P (2003) *Baby and Child* Dorling Kindersley Ltd

Lee K A, M E Zaffke and G McEnany (2000) Parity and sleep patterns during and after pregnancy *The American College of Obstetrics and Gynecologists* vol 95 no 1 pp14-18

Leininger M (1985) Transcultural care diversity and universality: a theory of nursing *Nursing Health Care* vol 4 pp208-212

Limerick S (1989) *Sudden Death in Infancy (Cot Death)* University of Exeter

MacQueen A and R Mander (2003) Tiredness and fatigue in the postnatal period *Journal of Advanced Nursing* vol 42 pp463-469

Miller LH, A Fraser, R Moy (2008) How does cot death prevention advice influence parents' behavior? *Child: Care, Health and Development* vol 34 (5) p613-615

Morris S, I St James-Roberts, J Sleep, P Gilharn (2001) Economic evaluation of strategies for managing crying and sleeping problems *Archives of Disease in Childhood* vol 84, no 1 pp15-19

Nikolopoulou M I St James-Roberts (2003) Preventing sleeping problems in infants who are at risk of developing them *Archives of Disease in Childhood* vol 88, no 2, pp108-111

Nishihara K, S Horiuchi (1998) Changes in sleep patterns of young women from late pregnancy to postpartum: relationships to their infant's movements *Percept Motor Skills* vol 87, pp1043-1056

NHS (2008) *Baby Sleep Video Advice* www.eyecatcher.tv/keeping_kids_healthy/kkh_advice.htm

- NSPCC (2008) *Coping with crying babies*
www.nspcc.org.uk/HelpAndAdvice/Parentsandcarers/CryingBabies/cryingbabie
- Polit D F, C T Beck, B P Hungler (2001) *Essentials of Nursing Research: Methods, Appraisal and Utilization* Lippincott
- RoSPA (2009) www.rospace.com
- Russell J A, J Bachorowski, J Fernandez-Dols (2003) Facial and vocal expressions of emotion
Annual Reviews of Psychology vol 54 pp329-349
- Sidey A and Widdas D (2005) *Textbook of Community Children's Nursing* Elsevier
- Sleep J, P Gillham, I St James-Roberts, S Morris (2002) A randomized controlled trial to compare alternative strategies for preventing infant crying and sleep problems in the first 12 weeks: the COSI study *Primary Health Care Research and Development* vol 3 pp 176-183
- Sleep J (2003) Where should infants sleep? A comparison of risk for suffocation of infants sleeping in cribs, adult beds and other sleeping locations *Pediatrics* vol112, no 4 pp883-889
- Sleep J (2007) *MCH 09-06: A randomised controlled trial to compare alternative strategies for preventing infant crying and sleeping problems in the first 3 months of life* DoH
- Southwell M T, G Wistow (1995) Sleep in hospitals at night: are patients' needs being met?
Journal of Advanced Nursing 21 (6) pp 1101-1109
- Spradley J (1980) *Participant Observation* Holt, Rinehart and Winston
- Swain AM, M W O'Hara, K R Starr and L L Gorman (1997) A prospective study of sleep, mood, and cognitive function in postpartum and non-postpartum women *The American College of Obstetricians and Gynecologists* vol 90 pp381-386
- Thompson N S, C Olson, B Dessureau (1996) Babies' cries: who's listening? Who's being fooled? *Social Research* vol 63, no 3
- Thornton A, C Morley, N Kohner (1991) *Baby Check* Blue Print
- Tonkin S, S A Vogel, L Bennet, A Jan Gunn (2006) Apparently life threatening events in infant car safety seats *BMJ* vol 333 pp1205-1206
- Understanding Childhood (2008) *Crying and Sleeping* www.understandingchildhood.net
- Young J and P Fleming (1999) Sudden infant death: reducing the risk *Community Practitioner* vol 72 No 7 pp201-205
- University of Brighton (2008) *Sleep Diary* UofB
- Wailoo M, S A Petersen, H Whittaker, P Goodenough (1989) Sleeping body temperatures in 3-4 month old infants *Archives of Disease in Childhood* 1989 vol 64 pp (596-599)
- Wilson R (2008) Cot death update *Science Direct* vol 18, 2 pp90-96

Appendix 1

Instructions for Parents

Thank you for agreeing to help us test this new product.

Lack of sleep is the thing parents/carers find most difficult in the first 6 months of a new baby's life and most of you complain that the thing you find hardest is shorter, broken nights...! Most of you find good ways to adjust to your new lifestyle. Sometimes this means parents/carers fall asleep in bed or on a sofa/chair with their baby. Lots of parents/carers do this and their babies are fine but it is also true that many of the babies who die suddenly and unexpectedly in the UK are found in bed or on the same sofa/chair as an adult. All cot death advice now recommends parents/carers place small babies (under 6 months) to sleep in the same bedroom as an adult but in their own cot, on their backs. It also recommends parents/carers avoid the temptation to cuddle babies to sleep on a sofa/armchair or in the parental bed. Other research warns about the dangers of leaving sleeping babies asleep in a car seat.....

The purpose of this study is to find out if using the Easidream™ mechanism can help babies to settle themselves to sleep. You will be asked to complete a sleep diary in the week before the trial so we can see what your baby's 'usual' sleep pattern is. This will enable us to compare before and after data for each baby.

The product itself has a separate (to the cot or mattress), battery run motor that sits within a 'self contained' platform. The mechanism is placed on the base of the cot with the mattress on top. The mechanism is regulated by a remote control panel and is able to rock/roll gently from either/both head to toe or side to side. There is a built in weight restriction - so the product will fail to work with babies over a certain weight (30lb).

All current recommendations about Sudden Infant Death Syndrome advises practices that can mean babies wake in the night so the Easidream™ aims to help small babies re-settle themselves (rather than simply staying asleep for long, perhaps dangerous, periods). The time-limiting facility is therefore crucial to the design, preventing parents/carers from using the device continuously and it will only work if an adult returns to the baby before re-setting the appliance. Safety is a major issue and the product complies with British Safety Standards.

To help the researchers compare your baby's sleep both before and with the Easidream™ mechanism we would be grateful if you would fill in the enclosed sleep diary for each sleep your baby has in the week before the study.

During the study, your baby will be settled to sleep in the way the current Department of Health guidelines recommend – on his/her back, with his/her feet placed at the bottom of the cot, covered in the total maximum 12 tog units recommended in an 18 C room temperature. It is important the research compares like with like and identifies where environments differ so we have asked you to tell us how (and when) your baby sleeps differently (or in the same way) at home.

For us to be sure you properly agree to your baby being part of this study we will need the parent/carer who attends with your baby to complete the attached consent form. We will go through the form with you before you sign it on the day of testing but a copy is enclosed here for you to consider in advance. If you have any queries about this or any aspect of the study before you and your baby attend please feel free to contact Maggie Stewart (on work and mobile contacts) or Victoria Molesworth (on work and mobile contacts).

If at any stage you feel you would like to complain about any aspect of the process but feel uncomfortable about speaking about it to either Maggie Stewart or Victoria Molesworth we have appointed 2 independent researchers to deal with these issues. You may contact Julie Scholes (Professor of Nursing, University of Brighton) on [telephone number] and Valerie Hall (Professor of Research) on [telephone number].

Appendix 2



University of Brighton

Easidream™ Sleep Diary to be used with each sleep (or as many sleeps as possible)

Baby's Name:		Date of Birth:	
Babies Weight: lbs or Kg			
		Date of using the sleep diary	
Time of sleep (please show am/pm)		Time of laying down (please show am/pm)	Time of waking (please show am/pm)
Please tick as many of these statements as are relevant to your baby for each sleep			
1. He/she was put down to sleep on his/her back			
2. He/she was put down to sleep on his/her side			
3. He/she was put down to sleep on his/her front			
4. He/she was put down to sleep with feet at the bottom of the cot			
5. He/she was put down to sleep differently to no 4 - please indicate how			
6. He/She was put down to sleep in the same way as normal			
7. He/she was put down to sleep because this is his/her usual sleep time.			

8. He/she was put down to sleep for a different reason to that in no 7 – please indicate why....	
9. He/she was put down to sleep after a usual feed	
10. He/she was put down to sleep after a feed but breast fed for less time than usual	
11. He/she was put down to sleep after a smaller bottle feed than usual	
12. He/she was put down to sleep after a longer/larger than usual breast/formula feed	
13. He/she took ____ minutes to go to sleep	
14. The time noted in 13 is similar to the usual time it takes to go to sleep	
15. He/she took longer than usual to go to sleep (please indicate in minutes how much longer)	
16. He/she took less time than usual to go to sleep (please indicate in minutes how much less)	

Easidream Research in XXXXX



- The University of Brighton is undertaking some research in this Nursery.
- We want to see if Easidream™ will help babies to sleep on their backs in a cot:
- The study will show us if Easidream™
 - helps babies settle and go to sleep on their own.
 - helps babies go to sleep (and stay asleep) safely
- We would like to watch babies asleep on the Easidream™
- Would you like your baby to take part?

For more information contact the researcher (Maggie Stewart) or the business lead for the study (Victoria Molesworth) at the University of Brighton, School of Nursing and Midwifery
m.stewart@brighton.ac.uk
v.molesworth@brighton.ac.uk

- THANK YOU for considering this request

Maggie Stewart has been a senior lecturer within the School of Nursing and Midwifery at the University of Brighton since 1991. Prior to this she was employed as a Research Health Visitor by the University of Sheffield.

Appendix 4 : Consent Form

An Observational Study of the Effectiveness of the Easidream™ cot accessory

Name of Researcher:

Please sign: Please initial box

1. I confirm that I have read and understood the information sheet - dated 17th January 2008 - about the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that the participation of my baby in the study is voluntary. I understand that this means I am free to withdraw my baby from the study at any time, without giving any reason and without my medical or legal rights being affected.	
3. I understand that the researcher will sit in the sleep room whilst my baby participates in the study. I understand that the researcher will take notes whilst my baby sleeps. I understand that aspects of these notes will be used to discuss the effectiveness of the Easidream™. I understand that all discussions about my baby's participation in the study will protect his/her identity and that the master copy of the notes will only be seen by members of the research team cited above.	
4. I have brought my baby to participate in the study on a day that I believe he/she is physically well. I agree to stay with my baby for the duration of the study. I also agree to be interviewed for this study.	
5. I agree to my baby being placed to sleep on the Easidream™ for this study	

_____ Name of participant's Parent/carer Signature	_____ Date	_____
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_____ Name of researcher Signature	_____ Date	_____
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Refreshed consent

_____ Name of participant's Parent/carer Signature	_____ Date	_____
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Appendix 5

Tog Table

Baby clothing and bedding	Average Tog value
Vest	0.2
Babygro	1
Jumper	2
Cardigan	2
Trousers	2
Nappy (disposable and terry)	2 (less when very wet)
Sleeping suit	4
Sheet	0.2
Old blanket (single layer)	1.5
New blanket (single layer)	2
Quilts	Manufacturers' figures (typically 9)

Standard "tog" values used to quantify the insulation on sleeping babies. Data supplied by the British Textile Technology Group (formerly the Shirley Institute) (Clulow, personal communication).